IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S,)
Plaintiff,)
v.) C.A. No. 05-645-SLR
SANOFI-AVENTIS, AVENTIS PHARMACEUTICALS INC., and AVENTIS PHARMA DEUTSCHLAND GMBH,) REDACTED) PUBLIC VERSION
Defendants.)

AVENTIS'S MOTION FOR ATTORNEY FEES

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I. INTRODUCTION

Aventis Pharmaceuticals Inc., sanofi-aventis, and sanofi-aventis Deutschland GmbH¹ (collectively "Aventis") hereby move the Court for attorney fees under Fed. R. Civ. P. 54(d)(2) and 35 U.S.C. § 285, based on the Court's Order of September 10, 2007 dismissing Novo's patent infringement claims with prejudice.

Although the grant of attorney fees is an extraordinary remedy, Novo's behavior in the present case warrants such an award to Aventis. First, Novo's prosecution of the patent-in-suit (U.S. Pat. No. 6,582,408, "the '408 patent") is riddled with examples of inequitable conduct, including a failure to disclose to the United States Patent & Trademark Office ("the PTO") Novo's own invalidating prior art patents and insulin pen device and a failure to disclose material from, or even the bare existence of, a co-pending, substantially similar Novo patent application. Second, Novo is developing a pattern of dragging Aventis into court to spend millions of dollars defending itself against unfounded allegations, only to have Novo drop its specious claims before Aventis is vindicated through a substantive finding on the merits. Accordingly, Aventis respectfully requests that the Court grant its motion and allow recovery of its reasonable attorney fees.

As the Court declined to hear dispositive motions in the present case, and because Novo moved to voluntarily dismiss its claims a mere month before trial was scheduled to begin, there have been no formal findings in the present case. However, due to the egregiousness of Novo's conduct, both in front of the PTO and during litigation in this and other courts, Aventis

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¹ Although the Complaint names Aventis Pharma Deutschland GmbH, this entity is now known as sanofi-aventis Deutschland GmbH.

respectfully asks the Court to consider the following facts² revealing the exceptional nature of the present case.³

II. BACKGROUND

A. The '408 Patent, the '011 Patent, and Novo's Own Prior Art

1. The Subject Matter of the '408 Patent

Throughout its prosecution history, the application from which the '408 patent issued ("the '408 application") has always included at least one claim requiring a "coupling means" between at least two of the three main parts of an injector—a dosing assembly, a cartridge assembly, and a needle assembly. Ex. A, '408 File History, p. SAN00761347. In addition, the documents to which the '408 patent claims priority include claims with the same limitation. Ex. H, '408 Priority Documents. The structure for the "coupling means" claim limitation is defined by the '408 patent specification as including snap couplings, such as snap locks. Ex. A, '408 patent, col. 3, lines 15–25, 30–37, p. SAN00761331. Novo argued during prosecution of the '408 application that relative, inadvertent rotation between the cartridge assembly and the dosing assembly could cause those parts to separate, resulting in the separation of an internal plunger means from a stopper of the cartridge, causing an inaccurate dose. Ex. A, p. SAN00761670. Therefore, Novo argued, it was necessary to select couplings between the dosing assembly and the cartridge assembly, and between the cartridge assembly and the needle assembly, that would prevent this rotation and the resulting separation. Ex. A, p. SAN00761672.

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² Many of the following facts are detailed at greater length in Defendants' Second Consolidated Answer and Counterclaims, D.I. 150, originally filed with the Court on November 7, 2006 and entered onto the docket on June 7, 2007.

³ See Interpart Corp. v. Italia, 777 F.2d 678, 686 (Fed. Cir. 1985) (affirming district court's finding of exceptional case status based on a failure to disclose highly material prior art during prosecution of the patent-in-suit, as well as an award of attorney fees, without formally deciding the issue of inequitable conduct).

During the course of prosecution, all independent claims of the '408 application were amended to require that at least one of these couplings be a "snap lock." Ex. A, p. SAN00761708-11. Novo argued that these amended claims of the '408 application were patentable over the prior art because they included a "snap lock," which, according to Novo, was not disclosed by the prior art. Ex. A, p. SAN00761706. On January 27, 2003, the PTO issued a Notice of Allowance of the '408 application stating that the claims of the '408 patent were "allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock." Ex. A, p. SAN00761714 (emphasis added). The '408 patent subsequently issued on June 24, 2003.

2. Novo's Own Prior Art Device

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Notwithstanding Novo's arguments to the PTO regarding the alleged novelty of the claims of the '408 patent, the couplings of the NovolinPen were configured to prevent the dosing inaccuracy discussed in the specification of the '408 patent. In the NovolinPen, the cartridge assembly is connected to the dosage assembly by way of a snap lock that is released through threads. Further, the high materiality of the NovolinPen is described in the corresponding '833

patent, entitled "Cartridge-Holder Assembly for Medication Dispensing Unit," which discloses a syringe-type medication dispensing unit that includes a cartridge, a cartridge holder, and a dosing assembly (referred to as a "dispensing device"). Ex. D, Abstract; col. 5, line 42–43. The dispensing device is designed so as to "prevent rearward movement of the plunger 5 once the [cartridge] housing 120 is in place." Ex. D, col. 6, lines 51–52. Indeed, the teaching of the '833 patent includes snap couplings:

The above device can be manufactured in many suitable materials and *readily lends itself* to manufacture by injection molding of suitable plastics materials with the *various components being snap fits* upon one another.

Ex. D, col. 9, lines 38–41 (emphasis added). The '833 patent further discloses a coupling means for coupling and uncoupling the cartridge holder (i.e., cartridge assembly) to and from the dispensing device (i.e., the dosage assembly) by way of a snap lock released through threads.

Ex. D, col. 5, lines 50-57; Fig. 9. Thus, both Novo's own NovolinPen and the corresponding '833 patent disclose a means for coupling a cartridge assembly to a dosing assembly that included a snap-lock coupling as claimed by the '408 patent.

3. Other Novo References and Their Materiality

Around the time the '408 application was prosecuted, the PTO granted Novo two patents directed to similar medication delivery device technology. However, as with the NovolinPen, Novo did not disclose either U.S. Pat. No. 6,004,297 ("the '297 patent") or U.S. Pat. No. 5,968,021 ("the '021 patent") during prosecution of the '408 application. The '297 and '021 patents both list on their faces Novo Nordisk A/S as the assignee. Ex. E, '297 patent; Ex. F, '021 patent.

The application that issued as the '297 patent was filed January 28, 1999, claiming priority to a provisional application filed February 5, 1998. The applications for the '297 patent

and the '408 patent were co-pending before the PTO for a short time, and the '297 patent issued some 3 1/2 years before the '408 patent issued. The '297 patent is entitled "Injection Syringe" and discloses a pen-type injector of a similar sort disclosed and claimed by the '408 patent. Additionally, the injector of the '297 patent includes a snap-lock coupling between the housing and the cartridge assembly, just like the '833 patent and the Novolin Pen:

The syringe comprise [sic] a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap-lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferantial [sic] groove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

Ex. E, '297 patent, col. 5, lines 35–43 (emphasis added).

Novo filed the application that issued as the '021 patent as a PCT application on February 27, 1995, and the application was published on August 3, 1995 and issued on October 19, 1999 as the '021 patent, some 9 months before the application for the '408 patent was filed. The '021 patent is entitled "Magazine and Removable Needle Unit" and discloses a needle unit having a sleeve "designed to be *snap-locked* onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece." Ex. F, Abstract (emphasis added). The summary of the invention states that "[t]he object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen type syringe and which may easily be dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe." Ex. F, col. 1, lines 46-50 (emphasis added).

Despite the relevance of these Novo prior art references to the '408 patent, including but not limited to the disclosure of snap locks, the Novo attorneys prosecuting the '408 patent failed to disclose them to the PTO.

4. The Parallel Prosecutions of the '408 Patent and the '011 Patent

For almost four years, Novo prosecuted two very similar patent applications in front of the PTO: the '408 application, and an application entitled "Medication Delivery Device" that issued as U.S. Pat. No. 6,562,011 ("the '011 application," "the '011 patent"), which lists Novo Nordisk A/S as its assignee. Ex. G, '011 File History, p. SAN00929518. These applications were filed within a day of each other with very similar priority claims—Novo had filed a pair of priority documents on each of July 8, 1998, September 1, 1998, and November 17, 1998, with each pair of documents being substantially identical, and with each pair providing one priority document for the '408 patent and one priority document for the '011 patent. Ex. I, '011 Priority Documents; Ex. H.

Indeed, the '408 and '011 patents themselves are substantially similar. They both name the same six inventors (and no others) and include the same three figures (and no others). Ex. A, p. SAN00761327; Ex. G, p. SAN00929518. The '408 patent lists fourteen references on its face, and the '011 patent lists sixteen references; nine of these references are shared between the two. Both patents list Marc Began under "Attorney, Agent, or Firm." Ex. A, p. SAN00761327; Ex. G, p. SAN00929518. There is also significant overlap between the disclosures of the two patents. For example, both patents discuss the problem of disengagement between the plunger means and the stopper means as well as the very same solution to that problem:

[I]t is a preferred aspect of the invention to provide a medication delivery device. which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly . . . [E]xamples of the

preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks.

Ex. A, '408 patent, col. 2, lines 54–58; col. 3, lines 23–25, p. SAN00761330–31.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly... . [E]xamples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks.

Ex. G, '011 patent, col. 2, lines 44-50, 59-61, p. SAN00929521. Additionally, both patents discuss a particular method of molding the cartridge assembly:

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge.

Ex. A, '408 patent, col. 3, lines 49-52, p. SAN00761331.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

Ex. G, '011 patent, col. 3, lines 23-24, p. SAN00929522.

Despite these pervasive similarities, Novo inexplicably treated these two applications as being completely irrelevant to one another during prosecution. In fact, Novo never even disclosed the copendency of the '011 application during the prosecution of the '408 application.4 Furthermore, even though the '833 patent (directed to Novo's own NovolinPen) was disclosed during the prosecution of the '011 patent in an Information Disclosure Statement dated January 26, 2000, it was never cited during prosecution of the '408 application. Ex. G, p. SAN00929202.

In a January 17, 2001 Office Action, the PTO rejected the claims of the '011 application as being anticipated or obvious over U.S. Pat. No. 6,146,361 ("the '361 patent"). Ex. G, p.

⁴ Novo also failed to disclose the copendency of the '408 application during prosecution of the '011 application.

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SAN00929386–89. In this Office Action, the examiner described the disclosure of the '361 patent in some detail, including a discussion of a dosing assembly, a cartridge assembly, the coupling means joining the two assemblies, and the fact that "the coupling[s] of the cartridge assembly are opposed." Ex. G, p. SAN00929387. Robert Smith, an outside attorney who substantively prosecuted both the '408 and the '011 patents between October 2000 and February 2002, responded to the Office Action on June 11, 2001—a response in which he discussed only the '361 patent and the claims of the '011 application. Ex. G, p. SAN00929401–05.

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The '361 patent was filed on September 26, 1996, and the prosecution of the '408 patent continued for more than two years after the '361 patent came to the attention of Novo and its prosecuting attorneys. The '361 patent discloses a needle assembly that could be snap-fit or snap-locked onto a cartridge retainer assembly:

Cap 56 of needle assembly 46 includes an array of internal threads (not shown) for removable mounting needle assembly 46 to needle mounting insert tip 20 on cartridge retainer assembly 10. It is to be understood, however, that other releasable engagement means between needle assembly 46 and cartridge retainer assembly can be provided. For example, external threads can be formed on needle assembly 46 and corresponding internal threads can be defined on cartridge retainer assembly 10 or a bayonet style mounting using lugs and slots can be used. In addition, needle assembly 46 could be "snap-fit" on to cartridge retainer assembly 10.

Ex. J, '361 patent, col. 3, lines 50-62 (emphasis added).

Despite the materiality of the examiner's analysis of the '361 patent to the claimed subject matter of the '408 patent, Novo never cited the January 17, 2001 Office Action during the prosecution of the '408 patent. Indeed, Novo failed to cite even the '361 patent itself.

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B. Novo's Egregious Litigation Conduct

Not content with trying to enforce an unenforceable patent, Novo has abused the legal system in this and other actions against Aventis. Novo is unlikely to break this pattern of bad faith behavior without the punitive sanction of having to pay Aventis's attorney fees. From the very outset, Novo has had no reasonable basis for pursuing the present action, but rather maintained it for the sole purpose of harassing Aventis and forcing Aventis to expend money and resources in its own defense. In line with this behavior, Novo has acted in bad faith by maintaining the present action and has instigated, and will likely continue to instigate, other baseless legal actions against Aventis solely for the purpose of harassment.

1. Novo's Tenuous Infringement Case

The threaded rod of Aventis's accused OptiClik device clearly resides with the cartridge assembly, a fact that can be ascertained upon casual inspection of the substantially transparent cartridge assembly. However, the claims of the '408 patent require that the threaded rod

("plunger") be a component in the dosing assembly; therefore, for this reason alone, the OptiClik device cannot infringe the '408 patent. This noninfringement position has been apparent from the very beginning of the present action, and yet Novo pursued the litigation without providing any substantive infringement analysis. In fact, when Aventis posed an interrogatory explicitly requesting that Novo detail its infringement claims, Novo objected, stating that Aventis prematurely asked for claim construction and expert testimony. Ex. P, Novo's Response to Interrogatory No. 1. Nevertheless, even when Novo served its expert report on infringement, it failed to include even a basic claim chart addressing how the claims of the '408 patent could conceivably be read on the OptiClik device.

When asked again to provide a meaningful claim construction and infringement analysis, Novo included a claim chart that merely parroted back the language of the claims with strings of document citations and vague references to the OptiClik device. Ex. P, Novo's Supplemental Response to Interrogatory No. 1. Indeed, Novo never even asserted that the piston rod ("plunger") of the OptiClik device was a part of the dosing assembly, as required by the claims of the '408 patent.

Over the course of almost two years of litigation, Novo was unable to offer a tenable infringement position. Novo's tenuous infringement position, coupled with the blatant, material omissions described above that riddle the prosecution history of the '408 patent and render it unenforceable, make it clear that Novo's pursuit of the present action is nothing more than litigation misconduct. Rather than trying to enforce legitimate patent rights, and indeed having no factual or legal basis for its contentions in the present action, Novo has been using the legal system in bad faith to harass Aventis.

2. Novo's Other Frivolous Legal Actions

On May 8, 2006, after filing and beginning to litigate the present action, Novo filed a Section 337 complaint with the ITC against Aventis alleging that the OptiClik device, and the Lantus and Apidra cartridge assemblies configured for use with the OptiClik device, infringe U.S. Patent No. 5,693,027 ("the '027 patent"). Ex. N, Complaint. Novo's complaint sought to permanently exclude the accused OptiClik products from entry into the United States, and also sought an order from the ITC enjoining Aventis from importing, marketing, offering for sale, or selling the accused OptiClik products in the United States.

During the ITC action, Aventis uncovered invalidating prior art references for the '027 patent, references that were no doubt known to Novo because they were Novo's own references. After realizing that Aventis knew of Novo's invalidating prior art, and with the completion date for the investigation set as August 23, 2007 and initial determinations due on May 23, 2007. Novo moved to terminate the ITC investigation and withdraw its ITC complaint on October 5, 2006. Ex. N, Initial Determination. The ITC granted Novo's motion on January 29, 2007. Aventis was forced to spend well over a million dollars defending itself against Novo's specious infringement allegations in front of the ITC.

In keeping with its bad-faith, litigious pattern, Novo filed yet another baseless lawsuit on July 10, 2007 in the District of New Jersey, alleging that Aventis's new pen device, the SoloSTAR, infringes another invalid and unenforceable patent. Ex. O, Complaint.

3. Novo's Motion to Dismiss

Novo moved to withdraw its complaint in this action on July 5, 2007, barely a month before trial was scheduled to begin on August 12, 2007. D.I. 152. Novo's reason for seeking dismissal on the eve of trial could not have been that there lacked sufficient damages to justify

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Moreover, only six weeks before filing its Motion to Dismiss, on May 16, 2007, Novo offered to settle this case if Aventis would agree to pay a sizeable sum of money. Novo maintained, until the very filing of its Motion to Dismiss, that this action was a legitimate effort at least to recapture economic loss inflicted by Aventis's past infringement with the OptiClik device. Given the economic incentive to continue this litigation, the fact that Novo moved to dismiss its complaint on the eve of trial indicates that Novo feared trial on the merits would expose the frivolous nature of its allegations. Nonetheless, Novo had already accomplished the goal of harassing Aventis and forcing it to pay for an expensive legal defense.

III. ARGUMENT

The United States Code provides for the recovery of attorney fees in patent cases: "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. Based on the Court's Order of September 10, 2007, Aventis is the prevailing party in the present case due to the dismissal of Novo's infringement claims with prejudice.

To be entitled to an award of attorney fees, the prevailing party must first show that the case is exceptional based on clear and convincing evidence and, second, that the award of attorney fees is appropriate. 35 U.S.C. § 285; *Phonometrics, Inc. v. Westin Hotel Co.*, 350 F.3d 1242, 1245 (Fed. Cir. 2003). The prevailing party can show that the case is exceptional through evidence of the non-prevailing party's "inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Id.* at 1246. Furthermore, the court can make an inference of bad faith "where

⁵ In an abundance of caution under Fed. R. Evid. 408, Aventis has not included the specific figure proposed by Novo. However, Novo's demand was made in writing and is available to the Court should the Court wish to review it.

the patentee is manifestly unreasonable in assessing infringement, while continuing to assert infringement in court . . . whether grounded in or denominated wrongful intent, recklessness, or gross negligence." *Id.* Once a finding of exceptional case status has been made, district courts have discretion to award attorney fees when appropriate. *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 781 F.2d 198, 201 (Fed. Cir. 1986).

The present case is exceptional for several reasons. First, Novo persistently engaged in inequitable conduct throughout the prosecution of the '408 patent, rendering it unenforceable. Novo also brought and subsequently withdrew another frivolous infringement case involving the OptiClik product in front of the ITC. Moreover, Novo persisted in pursuing the present case despite the unenforceability of the '408 patent, despite its tenuous infringement position, and long after its awareness of both deficiencies. If unchecked, Novo will undoubtedly continue its harassing, inappropriate use of the legal system against Aventis—indeed, Novo has already brought another patent infringement suit against Aventis involving Aventis's SoloSTAR device in the District Court of the District of New Jersey. Accordingly, Aventis asks the Court to recognize that an award of attorney fees is appropriate in the present case.

A. The Present Case Is Exceptional

1. Novo's Inequitable Conduct

Novo committed inequitable conduct during prosecution of the '408 patent, thus justifying a finding of exceptional case status, by (i) withholding the copendency of the similar '011 application; (ii) withholding a rejection of the claims of the '011 application; (iii) withholding the reference cited as a basis for that rejection; and (iv) not disclosing a prior art Novo device and other material Novo references. Failure to disclose information known by the patentee to be material to the patentability of the invention, such as a prior art reference or the

copendency of a similar application, will result in a finding of inequitable conduct. Inequitable conduct by the patentee may support a finding of exceptional case status and justify an award of attorney fees. Information regarding the patentability of an application is likely material to any similar copending application. Moreover, if a patentee was aware that information was material to the patentability of the invention but failed to disclose the information during prosecution of an application, the patentee's intent to deceive will be inferred. Here, Novo committed inequitable conduct during prosecution of the '408 application by repeatedly withholding information Novo knew was material to the patentability of the '408 application.

The law of inequitable conduct a.

A party may assert inequitable conduct by showing that the patentee intentionally failed to disclose information, such as a prior art reference, that the patentee knew was material to the patentability of the invention. Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362-1363 (Fed. Cir. 2003). The party asserting inequitable conduct must prove by clear and convincing evidence a threshold level of (i) materiality of the withheld information and (ii) intent to deceive the PTO during prosecution of the patent. McKesson Info. Solutions. Inc. v. Bridge Med., Inc., 487 F.3d 897, 913 (Fed. Cir. 2007) ("McKesson I"). Indeed, such inequitable conduct by the patentee may support a finding of exceptional case status and justify an award of attorney fees. 35 U.S.C. § 285; Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 182 F.3d 1356, 1358 (Fed. Cir. 1999).

⁶ Herein, Aventis uses for support three different decisions from the same action. The Federal Circuit opinion on inequitable conduct, McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 913 (Fed. Cir. 2007), will be referred to as "McKesson I." The district court opinion on inequitable conduct that was appealed to the Federal Circuit, McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 2006 WL 1652518, No. 02-2669 (E.D. Cal. June 12, 2006), will be referred to as "McKesson II." The later district court opinion on attorney fees, McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 2006 WL 2583025, No. 02-2669 (E.D. Cal. Sept. 6, 2006), will be referred to as "McKesson III."

Information such as a prior art reference is material if "a reasonable examiner would substantially likely consider [the information] important in deciding whether to allow an application to issue as a patent." McKesson I, 487 F.3d at 913. Information is not material if it is cumulative of information already disclosed to the examiner. Id. Intent to deceive the PTO is generally proven by inferences drawn from the facts rather than by direct evidence. Id. Intent to deceive is not inferred when the patentee provides plausible reasons for withholding the information, or when the patentee's conduct toward the PTO, in light of all the evidence, shows the patentee acted in good faith. Id. A court determines whether the patentee's conduct in withholding the information amounts to inequitable conduct by balancing the levels of materiality and intent. In establishing a finding of inequitable conduct, "a greater showing of one factor allow[s] a lesser showing of the other." Id.

> b. Novo's repeated inequitable conduct during prosecution of the '408 patent

Novo committed inequitable conduct during prosecution of the '408 patent, thus justifying a finding of exceptional case status, by (i) withholding the copendency of the similar '011 application; (ii) withholding a rejection of the claims of the '011 application; (iii) withholding the reference cited as a basis for that rejection; and (iv) not disclosing a prior art Novo device and other material prior art Novo references. Information regarding the patentability of a patent application is likely material to any similar copending application. McKesson I, 487 F.3d at 908; Dayco, 329 F.3d at 1368. Moreover, if a patentee was aware that information was material to the patentability of the invention but failed to disclose the information prosecution of an application, the patentee's intent to deceive will be inferred. McKesson I, 487 F.3d at 909. Here, Novo committed inequitable conduct during prosecution of

the '408 application by repeatedly withholding information Novo knew was material to the patentability of the '408 application.

> i. Novo committed inequitable conduct by withholding the copendency of the '011 application

A patentee does not fulfill its duty of disclosure by assuming that the examiner was aware of a rejection of a similar copending application. Manual of Patent Examining Procedure § 2001.06(b) (7th ed., 1998) ("MPEP"); McKesson I, 487 F.3d at 925-26. As the MPEP states:

Individuals . . . have a duty to bring to the attention of the examiner . . . information within their knowledge as to other copending United States applications which are "material to patentability" of the application in question. As set forth by the court in Armour & Co. v. Swift & Co., 466 F.2d 767, 779, 175 USPO 70, 79 (7th Cir. 1972):

[W]e think that it is unfair to the busy examiner, no matter how diligent and well informed he may be, to assume that he retains details of every pending file in his mind when he is reviewing a particular application . . . [T]he applicant has the burden of presenting the examiner with a complete and accurate record to support the allowance of letters patent.

Accordingly, . . . individuals . . . cannot assume that the examiner of a particular application is necessarily aware of other applications which are "material to patentability" of the application in question, but must instead bring such other applications to the attention of the examiner.

MPEP § 2001.06(b).

The Federal Circuit in McKesson I quoted the above passage from the MPEP, noting that the MPEP has put patentees on notice, since at least 1986, that patentees are not permitted to assume that the examiner was aware of actions related to a copending application. McKesson I, 487 F.3d at 925 ("[W]here inequitable conduct is at issue, mere possibilities [that the examiner was aware of actions related to a copending application] are insufficient.") (citing J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1564 (Fed. Cir. 1984)). Additionally, as PTO regulations require all disclosures be in writing, a patentee is not entitled to assume that an examiner was

aware of material information arising from a copending application absent a written disclosure to that effect. *McKesson I*, 487 F.3d at 925–26; 37 C.F.R. § 1.2 (2007); MPEP § 2002.02.⁷

The Federal Circuit stated that the MPEP "makes clear" that if copending applications involve similar subject matter and claims, the copendency "must be disclosed to the examiner of each of the involved applications." Dayco, 329 F.3d at 1365 (citing MPEP § 2001.06(b)) (quotations and alterations omitted, emphasis added). Novo should have disclosed at least the bare copendency of the similar '011 application during prosecution of the '408 application. The fact that the MPEP put Novo on notice of its duty to disclose such copendency strengthens the inference of intent to deceive the PTO. Moreover, "[t]he burden on patent applicants of advising the examiner of a closely-related pending application is slight" Eisai Co. v. Dr. Reddy's Labs., Ltd., 2007 WL 1437834, Nos. 03-9053, 03-9223, at *23 (S.D.N.Y. May 11, 2007). Because Novo withheld information that it knew was material to the patentability of the '011 application, Novo committed inequitable conduct by not disclosing the copendency of the '408 and '011 applications.

ii. Novo committed inequitable conduct by withholding the January 17, 2001 rejection of the claims of the '011 application

Novo committed inequitable conduct during prosecution of the '408 application by withholding from the examiner the January 17, 2001 rejection of the claims of the similar copending '011 application. A decision regarding the patentability of an application is likely material to any similar copending application. *McKesson I*, 487 F.3d at 908; *Dayco*, 329 F.3d at

⁷ MPEP § 2002.02 states that "[t]he action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt."

⁸ Evidence of good faith can negate inferred intent to deceive, and disclosure of the copendency in at least one of two copending applications can be that evidence of good faith. *Dayco*, 329 F.3d. at 1366. As Novo failed to cite the '011 application during the prosecution of the '408 patent, and failed to cite the '408 application during the prosecution of the '011 application, Novo cannot avail itself of such evidence of good faith.

1368. Moreover, when the patentee knew of the materiality of the information and nevertheless withheld the information from the PTO, the patentee's intent to deceive may be inferred.

McKesson I, 487 F.3d at 909, 924–25. Not only was the January 17, 2001 rejection material to the patentability of the '408 application because of the similarity between Novo's copending '408 and '011 applications, Novo knew of the materiality of the rejection and yet withheld this rejection from the examiner; thus Novo's intent to deceive may be inferred. Therefore, Novo committed inequitable conduct by withholding information that it knew was material to the patentability of the '408 application.

When a patentee is simultaneously prosecuting several similar patent applications, a decision of an examiner reviewing one of those applications is likely material to the copending applications as well. *McKesson I*, 487 F.3d at 919; *Dayco*, 329 F.3d 1358 at 1368. In *Dayco*, the copending applications "include[d] identical figures and substantially identical written descriptions" on identical subject matter, as well as "substantially similar claims." 329 F.3d at 1360, 1367. The Federal Circuit found that a rejection of an application containing claims that are "substantially similar" to those in a copending application is material to the copending application. *Id.* at 1368.

The Federal Circuit in *McKesson I* extended the reasoning of *Dayco* to hold that the claims in an application need not even be "substantially similar" for a rejection of the claims of an application to be material to a copending application. *McKesson I*, 487 F.3d at 919. Instead, the court applied the "reasonable examiner" standard, finding that a rejection of claims that are not substantially similar to a copending application may yet still be material to the patentability of the copending application. *Id.* at 919–20. Moreover, a decision of an examiner may be material even if only to support the patentability of an application. *Eisai Co.*, No. 03-9053, 03-

9223, 2007 U.S. Dist. LEXIS 34716, at *74 (S.D.N.Y. May 11, 2007) (citing Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1575 (Fed. Cir. 1996)). Therefore, a showing that two copending applications are similar suffices to make a decision on the patentability of one application material to a copending application.

A court may infer deceptive intent from a patentee's awareness that information was material to the patentability of an application in light of the patentee's failure to disclose the information during prosecution of a similar copending application. *McKesson I*, 487 F.3d at 909, 924–25. In *McKesson I*, the same attorney prosecuted two similar copending applications. *Id.* at 904. The district court found that

intent was inferable because [the patentee] was informed of the [undisclosed] patent's materiality by the PTO itself when [an examiner] brought the patent to [the patentee's] attention ... and then rejected claims as obvious in light of [the undisclosed patent]—including claim elements that were present in [a similar copending] application.

Id. at 909 (quotations omitted).

Novo committed inequitable conduct by not disclosing the January 17, 2001 rejection of the claims of the '011 application during prosecution of the '408 application. Like the copending applications in *Dayco* which "include[d] identical figures and substantially identical written descriptions," here, the '408 and '011 applications are substantially similar. 329 F.3d at 1360. Just as the patentee in *Dayco* should have disclosed the decision of an examiner reviewing a similar copending application, Novo should have disclosed the January 17, 2001 rejection of claims in the '011 application during prosecution of the '408 application. 329 F.3d at 1368. By failing to do so, Novo committed inequitable conduct.

The Federal Circuit's decision in *McKesson I* bolsters this conclusion. Two copending applications need not even have "substantially similar" claims for a rejection of claims of one application to be material to the other application. *McKesson I*, 487 F.3d at 919–920. The '408

and '011 applications well surpass the "substantially similar" threshold, and therefore the January 17, 2001 rejection of claims in the '011 application should have been disclosed during prosecution of the '408 application.

Novo could not have properly assumed that the examiner was aware of the rejection of claims of the '011 application. *Armour & Co.*, 466 F.2d at 779. Although the same examiner examined both the '408 and the '011 applications, the mere possibility that the examiner would have recalled an earlier rejection of the '011 application while examining the '408 patent is not sufficient to show that the examiner was aware of such material information. *McKesson I*, 487 F.3d at 909, 924–25.

Finally, because Novo can be charged with knowledge of the high materiality of the January 17, 2001 to the patentability of the '408 application, Novo's intent to deceive the PTO may be inferred. Similar to *McKesson I*, in which the same attorney prosecuted both similar copending applications, attorneys Robert Smith and Marc Began substantively prosecuted both the '408 and '011 applications. 487 F.3d at 904. Moreover, like the copending applications in *McKesson I*, the '408 and '011 applications are very similar. *Id.* Just as the attorney in *McKesson I* was aware of the materiality of the undisclosed information because of the similarity of the copending applications, Smith and Began were aware that the January 17, 2001 rejection of the claims of the '011 application was material to the '408 application because of the similarity of the '408 and '011 applications. *Id.* at 904, 909, 924–25.

Therefore, Novo committed inequitable conduct during prosecution of the '408 application by withholding the January 17, 2001 rejection of the claims of the '011 application, despite Novo's knowledge of the materiality of the rejection to the '408 application.

iii. Novo committed inequitable conduct by withholding the '361 patent

Not only did Novo commit inequitable conduct by withholding the January 17, 2001 rejection of claims of the '011 application during prosecution of the similar '408 application, Novo also committed inequitable conduct by withholding the '361 patent, cited as the basis for the rejection, during prosecution of the '408 application. When a patentee is simultaneously prosecuting several similar patent applications, a reference cited as the basis for rejecting claims of one of those application is likely material to patentability of the copending applications.

**McKesson I*, 487 F.3d at 919; **Dayco*, 329 F.3d at 1368. Not only was the '361 patent material to the patentability of the '408 application, Novo knew of the materiality of the '361 patent and yet withheld this reference from the PTO; thus Novo's intent to deceive may be inferred. Therefore, Novo committed inequitable conduct by withholding a reference that it knew was material to the patentability of the '408 application.

Novo committed inequitable conduct by not disclosing the '361 patent, cited as a basis for rejecting the claims of Novo's copending '011 application, during the prosecution of the '408 application. Like the copending patent applications in *McKesson I* and *Dayco*, the '408 and '011 applications were very similar and had significantly overlapping prior art disclosures. *McKesson I*, 487 F.3d at 904; *Dayco*, 329 F.3d at 1360. Moreover, like the examiner in *McKesson I*, the examiner here relied on an additional reference—the '361 patent—to reject the claims of the '011 application. 487 F.3d at 904–05. "[A]n examiner's reliance on a prior art reference in a related prosecution supports a finding of materiality." *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, No. 02-2669, 2006 WL 1652518, at *10 (E.D. Cal. June 13, 2006) ("*McKesson II*"). Here, that the examiner relied on the '361 patent for rejecting the claims of the '011 application

demonstrates that Novo violated its duty of candor by not disclosing the '361 patent during prosecution of the '408 application.

Novo's intent to deceive the PTO by withholding the '361 patent can be inferred. Mr. Smith, at least, had knowledge of the '361 patent, having discussed the reference in detail in his June 6, 2001 response to the January 17, 2001 Office Action. Additionally, both Messrs. Smith and Began prosecuted both the '408 and '011 applications. Just as the attorney in *McKesson II* was aware of the materiality of the undisclosed reference because of the examiner's reliance on the reference to reject claims in a similar copending application, Messrs. Smith and Began were aware of the materiality of the '361 patent to the '408 application when the examiner relied on this patent to reject claims in the similar copending '011 application. Because Messrs. Smith and Began were aware of the materiality of the '361 patent to the '408 application but did not disclose this reference, their intent to deceive the PTO may be inferred.

Therefore, Novo committed inequitable conduct during prosecution of the '408 application by withholding the '361 patent that Novo knew was material to the patentability of the '408 application.

iv. Novo committed inequitable conduct by withholding the '833 patent, the Novolin Pen, and the Novo references

Apart from the material references that arose during the prosecution of the related '011 application, there were multiple Novo prior art references withheld during the prosecution of the '408 patent. Novo certainly had knowledge of its own Novolin Pen and the corresponding '833 patent; however, neither the device nor the patent was disclosed to the PTO during prosecution of the '408 patent. Additionally, the '297 and '021 patents were both Novo references directed to medical delivery device technology similar to that of the '408 patent. Given that these

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⁹ Interestingly, Novo was cognizant enough of the materiality of the '833 patent to disclose it in a January 26, 2000 Information Disclosure Statement during the prosecution of the '011 patent.

references were all Novo's own references, and that these references are highly material both individually and in combination, it can be assumed that Novo withheld these references with the intent to deceive the PTO. Therefore, Novo violated its duty of disclosure by withholding this Novo prior art during prosecution of the '408 application, and thus, Novo committed inequitable conduct.

Novo's repeated nondisclosure of material information demonstrates a calculated scheme to defraud the PTO. Disclosure of any one of: (i) the copendency of the '408 and '011 applications, (ii) the January 17, 2001 rejection of the '011 application, (iii) the '361 patent cited as a basis for the January 17, 2001 rejection, and (iv) the '833 patent, the Novolin Pen, and the other material Novo references could very well have affected the scope and patentability of the '408 patent. Novo, however, disclosed none of this material information. The burden of disclosure is slight—no more than filing an Information Disclosure Statement. Because Novo withheld multiple references that it knew were material to the patentability of the '408 application with the intent to deceive the PTO, Novo committed inequitable conduct during prosecution of the '408 application.

> Novo's Repeated Failure to Disclose Material Information to the c. PTO Justifies an Award of Attorney Fees

Inequitable conduct by the patentee may constitute an exceptional case and, in turn, justify an award of attorney's fees. 35 U.S.C. § 285; Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 182 F.3d 1356, 1358 (Fed. Cir. 1999). Indeed, inequitable conduct alone may cause a case to rise to the level of an exceptional case. E.g., Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 804 (Fed. Cir. 1990). For example, a finding that the patentee withheld multiple material references and engaged in a program of withholding material information from the PTO may establish an exceptional case. E.g., Evident Corp. v. Church & Dwight Co., No.

97-3275 (MLC), 2003 U.S. Dist. LEXIS 26296, at *10 (D.N.J. June 30, 2003); Tarkett, Inc. v. Congoleum Corp., 156 F.R.D. 608, 614–15 (E.D. Pa. 1994); Halliburton Co. v. Schlumberger Tech. Corp., 722 F. Supp. 1433, 1434–35 (S.D. Tex. 1989). Novo failed to disclose multiple material references to the PTO, and based on the circumstances of that nondisclosure—including Novo's knowledge of the materiality of each withheld reference—it can be inferred that each failure to disclose occurred with an intent to deceive the PTO. Novo committed inequitable conduct repeatedly during the prosecution of the '408 patent; consequently, Novo's inequitable conduct rises to the level of an exceptional case.

A patentee engages in inequitable conduct justifying an award of attorney fees when the patentee withholds multiple material references from the PTO. Withholding a single material reference may not rise to the level of an exception case. E.g., Torin Corp. v. Philips Indus., Inc., 625 F. Supp. 1077, 1096–97 (S.D. Ohio 1985). However, the more references the patentee withholds, the more likely a court will find an exceptional case. For example, in Halliburton, the court found an exceptional case and granted attorney fees where the patentee failed to disclose four prior art references material to the patentability of the patent-in-suit and where the patentee was aware of the materiality of each undisclosed reference. 722 F. Supp. at 1434–35. Similarly, in Evident, the court awarded attorney fees where the patentee failed to disclose three prior art references. 2003 U.S. Dist. LEXIS 26296, at *10. Finally, in *Tarkett*, the court awarded attorney fees after finding that

[the patentee's] inequitable conduct was pervasive and egregious. . . . [The patentee] engaged in a series of deceptions to procure and preserve its . . . patent. This extended well beyond any mere isolated lapse in disclosing a potential prior art reference. Instead, it represented a general breakdown in the candor and good faith with which [the patentee] was expected to deal with the patent office. The result was the intentional concealment of at least three material references While the parties generated much heat at trial trying to define what a "pattern" is, the only "pattern" that an observer could not fail to recognize was plaintiff's pattern of deception.

156 F.R.D. at 614.

Inequitable conduct can also rise to the level of an exceptional case where the same few people committed the multiple instances of conduct in question. In *McKesson*, the same attorney prosecuted both copending applications. *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, No. 02-2669, 2006 WL 2583025, at *2 (E.D. Cal. Sept. 6, 2006) ("*McKesson III*"). The court found that this fact, along with the prevalence of inequitable conduct, strongly supported a finding that the attorney's conduct was an exceptional case. *Id.* at *5 (discussing "Schumann's non-disclosures").

Novo's conduct before the PTO clearly establishes a pattern of material nondisclosures that justified a finding of exceptional case status. Just as the patentees in *Halliburton, Evident*, and *Tarkett* withheld multiple material references, Novo's attorneys withheld not one mere reference; instead, they habitually failed to disclose material information such as (i) the copendency of the '408 and '011 applications, (ii) the January 17, 2001 rejection of the '011 application, (iii) the '361 patent cited as a basis for the January 17, 2001 rejection, and (iv) the '833 patent, the Novolin Pen, and the Novo material references. Moreover, the same attorney in *McKesson III* was responsible for the multiple nondisclosures, causing the court to find the case exceptional. Similarly, in the present case, Novo attorneys Messrs. Smith and Began withheld the multiple material references. *McKesson III* at *2, 6. Indeed, as Novo's nondisclosure of multiple material references evidences a "general breakdown" of Novo's duty of candor to the PTO, the Court should find that Novo's inequitable conduct justifies a finding of exceptional case status. *Tarkett*, 156 F.R.D. at 614.

2. Novo's Frivolous Lawsuit, Litigated Vexatiously and in Bad Faith

The prevailing party can prove vexatious litigation on the part of the non-prevailing party by showing, through clear and convincing evidence, that the non-prevailing party brought suit in bad faith. Eltech Sys. Corp. v. PPG Indus., Inc., 903 F.2d 805, 811 (Fed. Cir. 1990). In deciding whether a suit is vexatious, a court can consider the unreasonableness of the patentee in assessing infringement. Id. Where there is evidence that the patentee was "manifestly unreasonable in assessing infringement, while continuing to assert infringement in court," a court can properly infer bad faith, "whether grounded in or denominated wrongful intent, recklessness, or gross negligence." Eltech Sys. Corp., 903 F.2d at 811 (citing Phonometrics, Inc., 350 F.3d at 1246). Additionally, a pattern of making expansive claims that are later withdrawn 10 can constitute bad faith litigation where such a pattern causes the eventually prevailing party to expend "needless resources" conducting discovery, preparing a defense, and preparing for trial." Taltech Ltd. v. Esquire Apparel, Inc., 2007 WL 764776, at *36 (W.D. Wash, Mar. 9, 2007). In fact, the court in Taltech found that forcing an accused infringer to defend itself both in district court and before the ITC, and then withdrawing the ITC claims prior to the scheduled hearing, evidenced a pattern of vexatious litigation that supported finding a case exceptional. *Id.*

Novo's lawsuit began with frivolous allegations of patent infringement involving the OptiClik device, and Novo continued litigating long after the baselessness of the allegations became apparent. Indeed, Novo was manifestly unreasonable in assessing infringement in light

¹⁰ Some case law suggests that a voluntary dismissal can be indicative of good faith on the part of the plaintiff. Callaway Golf Co. v. Dunlop Slazenger, 384 F.Supp.2d 735, 747 (D. Del. 2005). However, in Callaway Golf Co., over the course of litigation, it came to light that the plaintiff's original analysis of the defendant's product was erroneous, and the plaintiff chose to voluntary withdraw its suit with prejudice. Id. In denying an award of attorney fees, the court concluded that the plaintiff brought the suit in good faith despite that "good faith" being based upon erroneous test data. Id. Because the plaintiff chose to voluntary dismiss the case when new information revealed no basis for suit, the plaintiff's voluntary dismissal of suit was "an indication of good faith." Id. In the current case, however, Novo's voluntary dismissal was allegedly triggered by information that was known by them for at least six months and came a scant month before trial; therefore, Novo is entitled to no such inference of good faith.

of the fact that the OptiClik device has a plunger in the cartridge assembly and the '408 patent claims a plunger in the dosing assembly; even after expert discovery had concluded, Novo failed to develop its infringement position beyond its original, deficient contentions. The clear unenforceability of the '408 patent, due to Novo's own, persistent, inequitable conduct, did not lend any credence to the lawsuit, either.

Novo's bad faith in pursuing the present action is underscored by its dubious excuse for waiting to withdraw its complaint a mere month before trial. Finally, Novo's litigation of a parallel infringement action against the same product and the same party (though inexplicably involving a different patent) in front of the ITC further demonstrates Novo's continuing pattern of harassing Aventis by dragging Aventis into court. That the ITC complaint was also voluntarily withdrawn before adjudication reveals that Novo is not protecting any legitimate interests through its litigiousness. Novo's frivolous suit, in combination with Novo's bad faith litigation conduct and Novo's pattern of expansive and later withdrawn claims, justifies a finding that the present case is exceptional.

The inequitable conduct committed during the prosecution of the '408 patent alone justifies finding exceptional case status. However, Novo has also pursued its baseless infringement allegations vexatiously and in bad faith. Therefore, Aventis urges the Court to find the present case to be exceptional, pursuant to 35 U.S.C. § 285.

B. Novo's Behavior Makes an Award of Attorney Fees to Aventis Appropriate

The award of attorney fees in exceptional cases is discretionary. S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201 (Fed. Cir. 1986). Factors for determining if attorney fees are appropriate include "the closeness of the case, the tactics of counsel, the conduct of the parties, and any other factors that may contribute to a fair allocation of the burden

of litigation as between winner and loser." *Id.* Among the properly considered tactics of counsel and conduct of the parties is any delaying tactics during discovery. *Philips Electronics North America Corp. v. Contec Corp.*, No. 02-123, 2005 WL 552509, at *6–7 (D.Del. March 8, 2005). When a basis exists for finding exceptional case status, a court may not deny an award of attorney fees without explanation. *S.C. Johnson & Son, Inc.*, 781 F.2d at 201 (vacating a denial of attorney fees when the trial court found willful infringement and did not articulate why case was not exceptional and deserving of fees).

The tactics of Novo's counsel and Novo's litigation conduct militate towards an award of attorney fees in the present case. Again, Novo revealed its bad faith in pursuing the present action through its conduct during settlement negotiations, by its dubious excuse for waiting to withdraw its complaint a mere month before trial, and by its failure to inform Aventis of the occurrence of a deposition that Aventis had properly noticed. Additionally, the ITC action that was filed, expensively litigated, and withdrawn, shows Novo's propensity to illegitimately use the legal system to harass, a propensity that is unlikely to change if Novo walks away from the current action unscathed. Only an award of attorney fees to Aventis will send a clear message to Novo that its pattern of baseless litigation is unacceptable.

The egregious pattern of inequitable conduct in which Novo engaged throughout the prosecution of the patent-in-suit further justifies an award of attorney fees. In *McKesson I*, the pattern of inequitable conduct was remarkably similar to that found in the present case. A single patentee was simultaneously prosecuting multiple formally unrelated but substantially similar applications, and the pattern of inequitable conduct mostly amounted to inconsistent disclosures for the copending applications. In an opinion separate from the inequitable conduct opinion, the district court found the pattern of inequitable conduct to be worthy of a finding of exceptional

case status but not for the award of attorney fees. Nonetheless, the reasoning of the district court in *McKesson III* provides guidance on why the present case is both exceptional and ripe for the award of attorney fees. In *McKesson III*, the plaintiff and its attorneys had not committed the inequitable conduct (having acquired the patent after the inequitable conduct had occurred), and the court held the patent to be unenforceable. The court reasoned that the mere fact of owning an unenforceable patent was sanction enough for a party personally innocent of inequitable conduct in front of the PTO, even for the egregious pattern of inequitable conduct.

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In the present case, however, the '408 patent has not changed ownership: it was Novo and its agents that committed the myriad instances of inequitable conduct during prosecution of the '408 patent, and it was Novo and its agents that insisted on asserting this flawed patent against Aventis for so long. Additionally, as this case was not adjudicated on the merits, Novo has not been punished with the sanction of unenforceability. Even if it is unlikely that Novo would again assert the '408 patent in litigation, it remains in the realm of possibility because Novo withdrew its suit before the '408 patent had been held unenforceable. Novo should suffer the impact of paying Aventis's attorney fees because it was and remains the culpable party that committed inequitable conduct in front of the PTO. Finally, based on the outcome of this lawsuit, Novo will suffer no sanction for its misconduct absent an award of attorney fees.

C. The Attorney Fees That Aventis Incurred in Its Defense Are Reasonable

Over the course of almost two years of litigation, Aventis has incurred attorney fees of over \$5 million defending itself against Novo's spurious claims. Should the Court grant the present motion, Aventis would be prepared to more formally audit the invoices so as to present the Court with a complete accounting of the attorney fees for Aventis's defense.

IV. CONCLUSION

For the foregoing reasons, Aventis respectfully requests the Court award Aventis reasonable attorney fees.

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